REMARKS

This paper is being filed in response to the non-final Office Action dated July 16, 2003. Claims 45-46, 49-60, 64-77, 79-80, and 82-87 were pending. Claims 51 and 66 are canceled herein without prejudice to Applicants' right to pursue the canceled subject matter in other applications. Claims 45, 50, 64 and 76 have been amended herein. Applicants submit that no new matter is introduced by these amendments. Accordingly, Claims 45-46, 49-50, 52-60, 64-65, 67-77, 79-80, and 82-87 remain pending.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 64-75 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner has objected to the recitation of the phrase "one or more nucleic acid molecules or selected from the group consisting of" found in claim 64 and recommended the deletion of the word "or." The Examiner also alleges that claims 65-75 are rejected for the same reason due to dependence on a rejected claim. In response, Applicants have amended claim 64 to delete the typographical error as kindly suggested by the Examiner. Accordingly, Applicants request the withdrawal of the rejection of claims 64-75.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 45, 46, 49-60, 64-77, 79, 80 and 82-87 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Examiner alleges that these claims contain subject matter which was not described in the

specification in such a manner as to reasonably convey to one skilled in the relevant art that the inventors, at the time of the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the phrase "chemical modification of any one of said nucleic acid molecules, wherein said modification produces a nucleic acid molecule having a length and nucleotide sequence which is the same as the nucleic acid molecule prior to modification," which is recited in claims 45, 64, and 76, constitutes new matter. Claims 46, 49-60, 65-75, 77, 79, 80 and 82-87 are also rejected on the same grounds due to their dependence on claims 45, 64, and 76. Applicants respectfully disagree with the new matter rejection.

Applicants assert that the specification provides sufficient support for the subject matter directed to the modification of nucleic acids, and thus no new matter has been introduced. The specification clearly defines a chemical analogue of a nucleic acid as a nucleic acid molecule having a modified base, nucleotide, nucleoside, or phosphate backbone (see, for example, page 25, lines 13-24 of the instant specification). The specification also provides examples of modifications to the nucleic acid molecules that are directed to protecting such molecules against nuclease digestion and thereby provide greater molecular stability of the antisense compound. These examples specifically recite the use of ethylphosphotriester linkage, 2'-O-methylribosyl derivatives, C-5 propyne substitutions, and other modifications to the bases or nucleic acid backbone that would be appreciated by one skilled in the art of antisense biochemistry as not altering the length and nucleotide sequence of the polynucleotide. Other examples are discussed in the cited references (see, for example, page 25, lines 26-28 of the instant specification).

Furthermore, the phrase "chemical modification" is a term of art in general biochemistry, and in particular would be plainly understood by the skilled artisan in antisense

biochemistry to mean a chemical modification that does not alter the length and nucleotide sequence of the polynucleotide, such as a covalently produced analogue of an antisense polynucleotide. See, e.g., The Oxford Dictionary of Biochemistry and Molecular Biology, Revised Edition, Oxford University Press, 2000, pp. 141, 424 (copy attached hereto). As such, Applicants' use of the term "modification" in the instant specification, which is congruent with the generally accepted understanding in the relevant art, refers to the creation of a modified base, nucleotide, nucleoside, or phosphate backbone of the antisense polynucleotide, and is wholly inconsistent with the position that any proposed "chemical modification" would alter the length or sequence of the antisense polynucleotide.

Indeed, upon a review of the specification, one of skill in the art would appreciate that the inventors had possession of the claimed invention. As discussed above, in the context of antisense biochemistry, modification of a nucleic acid in a polynucleotide does not imply to the skilled artisan that the length or sequence of the polynucleotide would be altered. On the contrary, one of skill in the relevant art would fully appreciate that any chemical modification of an antisense molecule would be performed to promote its stability for therapeutic purposes, and it is universally recognized that changes in the length or sequence of an antisense polynucleotide would result in unintended, and likely undesirable, effects on its therapeutic efficacy.

Pursuant to MPEP 2163.04, a description as filed is presumed to be adequate, unless or until sufficient evidence has been presented by the examiner to rebut the presumption. *In re Wertheim* 541 F.2d 257, 262, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976). The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim* 541 F.2d 263, 191 U.S.P.Q. at 97.

The Examiner has merely stated that she was unable to find support for the limitation, and without Applicants' identification of such support, concluded that the limitation is new matter. The Examiner has provided no evidence, however, that one of skill in the art would not recognize that the present specification clearly discloses that the modified nucleic acid molecule of the claimed invention would have a length and nucleotide sequence which is the same as the nucleic acid molecule prior to modification. Applicants have pointed above to support within the instant specification and in the art. Especially in light of the specification's use of the term "modification" and widespread use of this term in the relevant art to support Applicants' construction of the term, Applicants respectfully submit that the Examiner's burden of presenting evidence of construction that is contrary to accepted usage has not be met.

As such, withdrawal of the claim rejections under 35 U.S.C. § 112, second paragraph is respectfully requested.

Rejections under 35 U.S.C. § 102(b)

The Examiner has maintained the rejection of claims 45, 46, 49, 50, 51, 54 and 64-66 under 35 U.S.C. § 102(b) as allegedly anticipated by WO 96/01636 to Werther et al. The Examiner alleges that Werther et al. disclose methods of treatment for proliferative and inflammatory skin disorders, including psoriasis, using an antisense oligonucleotide consisting of SEQ ID NO:10 in a pharmaceutically acceptable carrier.

In response, Applicants have canceled without prejudice all subject matter reciting SEQ ID NO:10 in claims 45 and 64. In addition, claims 51 and 66 have been canceled without prejudice. As amended, claims 45 and 64 are not anticipated by Werther et al.

Therefore, Applicants submit that claims 45 and 64, and their dependent claims 46, 49, 50 and 65, are now allowable.

Claim 54 does not recite SEQ ID NO:10. Therefore, Applicants believe that this claim has been erroneously rejected as anticipated by Werther et al.

In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the rejection of claims 45, 46, 49, 50, 51, 54 and 64-66 under 35 U.S.C. § 102(b).

CONCLUSION

In view of the foregoing amendments and remarks, favorable consideration and allowance of all pending claims is earnestly solicited.

Attorney Docket No. AP32556-071838.0125
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Applicants attach herewith a fee transmittal authorizing the extension fee pursuant to 37 C.F.R. §§ 1.136(a) and 1.17(a)(3) for reply within the third month. No fee, other than the three-month extension fee, is believed due in connection with this submission. However, if any additional fee is required in connection with this communication, the Commissioner is hereby authorized to charge such fee pursuant to 37 C.F.R. §1.17(p) to Deposit Account No. 02-4377. A duplicate copy of this page is enclosed.

Respectfully submitted,

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Attachments